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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,804	09/19/2003	Herbert E. Schwartz	FZIO-01000US6	8739

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EXAMINER

CRANE, LAWRENCE E

ART UNIT PAPER NUMBER

1623

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/666,804	Applicant(s) SCHWARTZ ET AL.	
	Examiner L. E. Crane	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-66 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4 documents</u> . | 6) <input type="checkbox"/> Other: ____ |

No claims have been cancelled, no claims have been amended, the disclosure has not been amended, and no new claims have been added as of the date of the Office action. Four Information Disclosure Statements (4 IDSs) filed April 25, 2005, August 25, 2005, October 27, 2005 and November 18, 2005 have been received with all cited references and made of record. See individual IDS's for references not made of record for lack of complete bibliographic information.

The disclosure is objected to because of the following informalities:

The first paragraph of the disclosure is not up to date because it fails to provide patent numbers for all issued applications.

Appropriate correction is required.

Note to applicant: Reference "CC4" (EP 0 264 719) does not appear to be an appropriate reference (no technical terms seen which suggest relevant subject matter. Is this the correct reference serial number?

Claims 1-66 remain in the case.

Note to applicant: when a rejection refers to a claim X at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims 1-25, 29-49, 52-57 and 65-66 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention; the scope is excessive in view of the disclosed enabling exemplifications.

The assertion of an "analgesic" or pain inhibiting effect in claim 1 and again in claims 30, 31, 34, 36, 38, 39, 40 and 65 is not accompanied by any data in the instant disclosure to support the asserted analgesic effect of the compositions of claim 1 alone. Examiner finds only disclosure that the instant claim 1 compositions can be amended to include an "analgesic" or other "drug." Clarification of the factual basis for the implied "analgesic" activity in the noted claims is respectfully requested.

Claims **1-57, 60 and 65-66** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims **1-57 and 65-66** are indefinite because the noted claims have failed to provide for the presence of a specific analgesic substance (possibly excepting claims **26-28 and 50-51**). Is applicant claiming that the mixture of polymers and metal ions in claim 1 has inherent analgesic properties, or must an analgesic be present for the pain inhibiting effect to be observed? Clarification is respectfully requested. As examiner has noted above, no data has been provided to indicate the answer to this query.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim(s) 3 at line 5 recites the broad recitation “including,” and the same claim at line 2 also recites “group consisting of” which is the narrower statement of the range/limitation. Appropriate clarification is respectfully requested.

Claim **50** is an exact duplicate of claim **26**. Applicant is respectfully requested to cancel one of the noted claims or to take other appropriate action to remove the duplication.

In claim **60** at line 3, the abbreviation “(7HF)” is not defined. An appropriate definition of the entire term “CMC (7HF)” is respectfully requested to be included in the claim.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the

“right to exclude” granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **58-61** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-42** of U. S. Patent No. **6,869,938** (PTO-1449 ref. **BB44**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the carboxypolysaccharide/polyether/polyvalent cationic gels and membranes claimed are directed to substantially overlapping subject matter.

Claims **58-61** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-19** of copending Application No. **10/995,448** (see also PG PUBS equivalent **US2005/0074495**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the carboxypolysaccharide/polyether/ polyvalent cationic gels and membranes claimed are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **58-61** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim **13** of copending Application No. **11/189,510** (see also PG PUBS equivalent **US2006/0035861**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the

carboxypolysaccharide/polyether/ polyvalent cationic gels and membranes or compositions claimed are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **62-64** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim **20** of copending Application No. **10/995,448** (see also PG PUBS equivalent **US2005/0074495**). Although the conflicting claims are not identical, they are not patentably distinct from each other because all of the noted claims are directed to administration for inhibiting surgically related adhesions of carboxypolysaccharide/polyether/polyvalent cationic gels and are therefore substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

“A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.”

Claims **58-61** are rejected under 35 U.S.C. §103(a) as being unpatentable over **Hercules Cellulose Gum** (PTO-1449 ref. **23DD**). (An equivalent disclosure appears in the **AQUALON** reference {PTO-892 ref. **12DD**; publication date not yet established}.)

The instant claims are directed to compositions comprising carboxymethylcellulose, polyethyleneoxide and a metal ion.

Hercules Cellulose Gum discloses at page 23, column 2 through page 24 that cellulose gum (aka carboxymethylcellulose) is known to be miscible with “most water soluble non-ionic gums over a wide range of concentrations.” Cellulose gum is also known in the art to be compatible to varying degrees with inorganic salts as disclosed on page 21 including salts of calcium, aluminum, ferric and ferrous, and zinc ions.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to mix all three types of compounds (CMC, a water soluble gum including polyethylene oxide and a metal salt) to produce the instant claimed compositions.

Therefore, the instant claimed compositions would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for

unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < <http://pair-direct.uspto.gov> >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LECrane:lec
06/11/2006

A handwritten signature in black ink, appearing to read 'L. E. Crane', is written over a horizontal line.

L. E. Crane, Ph.D., Esq.
Primary Patent Examiner
Technology Center 1600